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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,006	03/22/2004	Ashley J. Birkett	91644	1250
24628	7590	02/26/2007	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			PENG, BO	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/806,006

Applicant(s)

BIRKETT, ASHLEY J.

Examiner

Bo Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006 and 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-97 and 110-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-97 and 110-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/06&11/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2006 has been entered.
2. This Office Action is in response to the amendment filed September 21, 2006. Claims 79-97 and 110-115 are pending, and are under consideration in this Office action.

Information Disclosure Statement

3. Applicant's IDS form 1449 submitted on September 21, and November 22, 2006 has been considered by the examiner. The initialed and dated copies of IDS form 1449 are attached to the instant Office action.

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of Claims 79, 80, 82-97, 110, 111 and 113-115 under 35 U.S.C. 103(a), as being obvious over Ireland (US 5,990,085), in view of Zlotnick (1997) **is maintained**, now is included Claim 112.

6. The rejection of Claims 79-97 under 35 U.S.C. 103(a), as being obvious over Zlotnick and further in view of Pumpens et al. (1995), **is maintained**.

7. The rejection of Claims 79-82 and 110-112 under 35 U.S.C. 103(a), as being obvious over Thornton (US 5,143,726) in view of Zlotnick et al. (1997), **is maintained**.

In response to Applicant's arguments:

8. Applicant argues that the Zlotnick teaching is not properly combinable with any other relied-on disclosure because an Ala for Cys substitution taught by Zlotnick is not "conservative", while all of the claims recite that the substitutions present are conservative (Remarks paragraph 3, p. 13).

9. In response to applicant's arguments against the cited references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, the instant claims encompass HBc chimer containing C-terminal deleted native HBc Δ and no more than about 5% conservatively substituted amino acid residues in the native HBc sequence. Thus, the instant

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claims include HBc chimera in which HBc Δ is from native HBc. Applicant is reminded the teaching of Ireland and Pumpens, in which they teach the C-truncated HBc Δ contains all native residues.

10. Moreover, the previous Office actions pointed out that Zlotnick *et al.* teaches adding a C-terminal cysteine residue to achieve a stabilizing effect (See p. 9556 and 9558) (see Final Office action, paragraph 21-23). To illustrate this, Zlotnick has shown that the Cp*150 construct that contained no internal Cys and had a C-terminal Cys is more stable than the Cys-free construct Cp*149, suggesting that disulfide bond formation by Cp*150 can promote capsid assembly (Results and Discussion, paragraph 1 and 2, p. 9558). Thus, Zlotnick has provided the knowledge of minimal determinant of HBV capsid assembly, which which has provided general knowledge that would lead one of ordinary skill in the art to combine the relevant teachings of the references. One of ordinary skill in the art would apply this general knowledge of HBV assembly to the construction of HBc chimera.

11. Applicant argues again that Pumpens' statement that foreign insertions exert a stabilizing effect on chimeric HBc Δ lacks legitimacy because it is based on unpublished results is not convincing because Pumpens' statement is published as a written record. In addition, this statement "leads away from the present invention whose active agent gains stabilization from an added C-terminal cysteine" (Remarks paragraph 1, p. 15).

12. In response, first, a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See In re Gurley, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). Here in contrast to

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applicant's assertions of teaching away by Pumpens because the references indicate a successful HBcΔ chimers; there is neither discouragement nor skepticism in the prior art for HBcΔ chimers. Secondly, as discussed in this and previous office actions, the feature of "the present invention whose active agent gains stabilization from an added C-terminal cysteine" is taught and suggested by Zlotnick. Therefore, the combine teaching of cited reference of Ireland, Pumpens, Thronton and Zlotnick does not constitute teaching away from the alleged invention.

13. Applicant also argues that Ulrich, as ordinary skill in the art, who stated that the stability problem of HBc was not solved, did not suggest that the desired stability could be achieved by combining teachings of Ireland, Pumpens, Thronton and Zlotnick, but rather maintained that the problem had yet to be solved (Remarks, p. 18).

14. Applicant's argument is not relevant. Even though Ulrich did not combine teachings of both Pumpens and Zlotnick, the knowledge of Pumpen and Zlotnick are still suggestive to those of ordinary skill in the art. In the instant claims, specifically, all basic structural feature limitations are taught or suggested by Ireland, Pumpens, Thronton and Zlotnick. Applicant has not explicitly pointed out which specific structures of the alleged HBc chimera are different from the prior art, and how they result in the alleged stability of the claimed HBc chimera. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

15. The following are new rejections:

Claim Rejections - 35 USC § 112, first paragraph

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 79-97 and 110-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection affects all dependent claims.

18. Please note that the newly amended scope of “cysteine residues of (ii), said recombinant chimeric HBc protein molecules “being more stable on storage at 1 mg/mL using 50 mM NaPO₄, pH 6.8 than are particles formed from an otherwise identical HBc chimera molecule that lacks said C-terminal cysteine residue or in which a C-terminal cysteine residue present in the chimera molecule is replaced by another residue” in Claims 79 and 80 is NEW MATTER.

19. A survey of the specification failed to find support for that said recombinant chimeric HBc being “more stable on storage at 1 mg/mL using 50 mM NaPO₄, pH 6.8 than are particles formed from an otherwise identical HBc chimera molecule that lacks said C-terminal cysteine residue or in which a C-terminal cysteine residue present in the chimera molecule is replaced by another residue”. Removal of all new matter is required. *In re Russmussen* 210 USPQ 325.

Conclusion

20. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP
Bo Peng, Ph.D.
2/14/07

Bruce Campell
BRUCE R. CAMPPELL, PH.D
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